

## **REMARKS**

Claims 1, 8, 10 and 13-20 are cancelled.

Claims 21-42 are new. The discussion of the prior art cited in the Office Action dated September 6, 2011, is made in light of the subject matter of claims 21-42.

All pending claims depend from independent claim 21, wherein claim 21 is drawn to a composition comprising a tablet for oral administration. The active components of the tablet comprise a solid extract of a deep sea fish having a protein content in the range of about 15-70 wt%, and rooibos extract in a range of about 5 to 40 mg. The tablet of claim 21 also comprises one or more fillers or ancillary agents conventionally used in the formulation of tableted pharmaceutical compositions.

### **The Subject Matter Of Claims 21-42 Is Supported By A Written Description In The Specification. Claims 21-42 Are Patentable Under 35 U.S.C. § 112, First Paragraph.**

Claims 1, 8, 10 and 13-20 are cancelled in response to the Examiner's rejection on page 2 of the Office Action dated September 6, 2011.

Claims 21-42 are new and fully supported by a written description in Applicant's specification. Therefore, the rejection under 35 U.S.C. § 112, first paragraph, is obviated in light of claims 21-42.

**The Subject Matter Of Claims 1, 8 and 13-17 Would Not Have Been Obvious From A Combination Of Tokumaru And Kujiyou. Claims 1, 8 and 13-17 Are Nonobvious Under 35 U.S.C. § 103(a).**

Tokumaru discloses a health food which comprises active and auxiliary ingredients that provides a health effect to the human body without impairing the flavor of a milk fermentation product. JP 09191852 A (“Tokumaru”), paragraph [0001].

The Examiner cites Tokumaru for teaching, among other things, shark cartilage and 1.5 g shark fin extract. 9/6/2011 Office Action, p.4. However, Tokumaru does not teach the limitation of claim 21, which requires the protein extract from a deep sea fish to be in the range of about 15-70 wt%.

The Examiner correctly states that Tokumaru discloses a health food composition that may be in the form of a tablet. However, the tablet of Tokumaru is comprised of materially different active ingredients than what is required in the present invention. *See* Tokumaru, paragraph [0001] (stating field of the invention drawn to composition “without starting [sic] the health food which gives the health effect to a human body, and [without] impairing the flavor of a milk fermentation product”); *see also* id., paragraph [0036] (stating active ingredient of a milk fermentation product principally comprised of calcium salt and oligosaccharides). Therefore, Tokumaru is at best cited for the teaching of a tablet having the flavor of a milk fermentation product.

The Examiner combines Tokumaru with Kujiyou for teaching extract of rooibos (*Aspalathus linearis*).

Kujiyou discloses a method for preparing Rooibos Tea. The method consists of the steps of selecting fresh or dry branches and leaves of rooibos, fermented products or mixtures thereof,

and extracting with 2-200 wt. times of water solvent with pH of 7-12 at 40-100 degrees Celsius for 15 minutes to 4 hours. JP 07039339 A (“Kujiyou”), Abstract. However, the Examiner states:

Tokumaru et al teach the rooibos tea extract is extremely excellent in palatability, and has wide range of fields such as health food and drink [0030].

9/6/2011 Office Action, page 5, lines 13-14.

Applicant believes the Examiner intended to cite paragraph [0030] of Kujiyou - and not Tokumaru - which make similar, yet materially different disclosures. In contrast to the disclosure of Tokumaru, paragraph [0030] of Kujiyou teaches:

While extracting polyphenol efficiently, it is very useful that manufacture of the rooibos tea extract which was extremely excellent in palatability is attained without impairing the good color tone and flavor which rooibos tea originally has, and the use to a wide range of fields, such as health food and a drink, opens etc.

*Id.* Thus, Kujiyou teaches extraction of polyphenol in the manufacture of rooibos tea, wherein the palatability and color of the tea are preserved.

However, Kujiyou does not teach the limitation required in claim 21 of the present invention - *i.e.*, an extract of rooibos (*Aspalathus linearis*) in a range of about 5 to 40 mg.

Further, Tokumaru, whose disclosure is drawn to the flavoring of a fermented milk product, does not appear to teach, suggest or motivate its combination with the disclosure for the manufacture of rooibos tea found in Kujiyou.

The Examiner notes on pages 6 and 7 that the result-effective adjustment in conventional working parameters is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan, and the differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art

unless there is evidence indicating such concentration or temperature is critical. *See* 9/6/2011 Office Action, pp.6-7.

A particular parameter must first be recognized as a result-effective variable, i.e., a variable which achieves a recognized result, before the determination of the optimum or workable ranges of said variable might be characterized as routine experimentation. In re *Antonie*, 559 F.2d 618, 195 USPQ 6 (CCPA 1977) (The claimed wastewater treatment device had a tank volume to contractor area of 0.12 gal./sq. ft. The prior art did not recognize that treatment capacity is a function of the tank volume to contractor ratio, and therefore the parameter optimized was not recognized in the art to be a result- effective variable.).

Here, the prior art fails to indicate that the amounts required in the claimed subject matter is critical. Applicant's specification sets forth specific amounts which depend upon several factors not set forth in the prior art, for example: (a) the type of pathological condition, and (b) whether the composition is to be topically administered or orally administered.

Therefore, claims 21-42 are nonobvious under § 103(a) in light of the references of Tokumaru and Kujiyou.

**The Subject Matter Of Claims 21-42 Would Not Have Been Obvious From A Combination Of Strumor And Kato. Claims 21-42 Are Nonobvious Under 35 U.S.C. § 103(a).**

The Examiner cites Strumor for teaching a tablet for aiding memory comprising 200 mg of shark cartilage and 16 other components with total weight of the tablet at 2281 mg. 9/6/2011, pp.7-8. U.S. Patent No. 6,149,939 (“Strumor”).

However, Strumor does not teach the limitations required in the present invention as claimed. Claim 21 requires, among other features, the limitation of a solid extract of a deep sea fish comprising protein, the protein extract being in a percentage range of about 15-70 wt %.

Kato is cited for teaching a therapeutic agent for stimulating cerebral metabolism and improving cerebral function. 9/6/2011 Office Action, p.8. The disclosure of Kato asserts that the preparation containing Aspalathus linearis extract can be used for stimulating brain metabolism of mammals including humans, improving memory and brain function, treating or improving brain and nervous diseases such as senile dementia and Parkinson disease, without side effects. JP 05246866 A (“Kato”), Abstract.

Applicant notes that the teachings of Kato is not reasonably related to the subject matter of the present invention.

Therefore, Strumor and Kato, alone or in combination fail to teach, suggest, or motivate Applicant’s claimed invention which requires a composition drawn to the treatment of age-related dermatological symptoms.

## CONCLUSION

It is respectfully submitted for reconsideration that pending claims 21-42 are in condition for allowance and notification to that effect is respectfully requested. The Examiner is invited to contact Applicant's Representatives at the telephone number listed below if it is believed that prosecution of this application may be assisted thereby.

Respectfully,

/James C. Wray/

James C. Wray, Reg. No. 22,693  
1493 Chain Bridge Road, Suite 300  
McLean, Virginia 22101  
Tel: (703) 442-4800  
Fax: (703) 448-7397

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